REMARKS

Claim Amendments

Claims 31, 32, 34 and 35 are amended to delete an instance of the term "about". No new matter has been added. Upon entry of the amendments, claims 12-14, 16, 18-20, 22, 24-25, 27-28, and 30-35 will remain pending in the application.

Rejection Under 35 U.S.C. § 103

Claims 12-14, 16, 18-20, 22, 24-25, 27-28 and 30-35 stand rejected under 35 U.S.C. §103(a) as being obvious over Breivik et al. (U.S. Pat. No. 5,502,077) in view of Harrison's Principles of Internal Medicine. Applicants submit that the rejection is traversed for the reasons set forth below.

1. The Examiner has failed to establish a prima facie case of obviousness.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of prior art references; and the references, when combined, must teach all of the claim limitations. See MPEP 2143. Furthermore, "to reach a proper conclusion under §103, the decisionmaker must step backward in time and into the shoes worn by [a person having ordinary skill in the art] when the invention was unknown and just before it was made. In light of all the evidence, the decisionmaker must then determine whether . . . the claimed invention as a whole would have been obvious at that time to that person." In re Fine, 837 F.2d 1071, 5 USPQ2d 1596,1598 (Fed. Cir. 1988) (citing Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566, 1 USPQ2d 1593, 1595-96 (Fed. Cir. 1987)).

As defined in amended claims 12, 18, 24 and 27, the present invention is directed to the use of essential fatty acids with a high content in EPA-ethyl ester, DHA-ethyl ester or a high concentration mixture of EPA-ethyl ester and DHA-ethyl ester for reducing the reoccurrence of adverse cardiovascular events in a patient who has survived a myocardial infarction. As further described below, neither of the cited references remotely teaches or suggests the use of essential fatty acids for the secondary prevention of adverse cardiovascular events in a patient who has

survived a myocardial infarction. Thus, Applicants submit that the cited references do not provide the necessary motivation or suggestion to combine the reference teachings; and, even if combined, the references do not teach all of the claim limitations of the present invention.

As acknowledged by the Examiner, the principal reference, Breivik et al., differs from the present invention in that Breivik et al. do not teach the administration of fatty acids to a patient who has suffered from a myocardial infarction. Instead, Breivik et al. report a study of hypertension, hypertriglyceridemia and high coagulation factor VII phospholipids complex activity in otherwise healthy patients having undetected moderate hypertension without previous cardiac illness or cardiac drug use. See Col. 6, lines 20-37 of the reference. Although the Examiner is correct in pointing out that the cited reference describes the administration of fatty acids to the general population for the improvement of particular cardiovascular risk factors, Applicants maintain that Breivik et al. cannot be said to remotely teach or suggest the administration of fatty acids for the secondary prevention of adverse cardiovascular events in patients who have survived a myocardial infarction.

The deficiencies of the principal reference cannot be overcome by resorting to the teachings of Harrison's Principles of Internal Medicine. The Examiner has relied on Harrison's "to show that myocardial infarction patients was a population known to the skilled artisan and that myocardial infarction was known to be associated with the risk factors identified and treated by Breivik et al." See page 4 of the October 21, 2005 Office action. However, Applicants submit that the Examiner has misconstrued the teachings of Harrison's. In particular, in the May 23, 2005 Office action, the Examiner cites Harrison's at page 1066, Col. 1 wherein it is stated that myocardial infarction is a result of thrombotic occlusion of a coronary artery resulting from a vascular injury "produced or facilitated by factors such as cigarette smoking, hypertension and lipid accumulation." Such teaching relates to the development of myocardial infarction in the general population rather than the secondary prevention of adverse cardiovascular events in a patient who has survived a myocardial infarction. Thus, the Examiner has failed to point out the necessary teaching or motivation for one skilled in the art to combine Harrison's with Breivik et al. to practice the present invention related to the secondary prevention of adverse cardiovascular events after myocardial infarction.

Further, Applicants submit that the Examiner has erred in not looking at Harrison's in its entirety. In particular, Harrison's actually contains teaching contrary to the Examiner's conclusion which supports the Applicants premise that patients having suffered a myocardial infarction are distinguishable from the general population. For example, at page 1066, Harrison's states that a "risk of excess mortality and recurrent nonfatal myocardial infarction persists in patients who recover" from myocardial infarction. Further, at page 1076, Harrison's discusses "postinfarction risk stratification and management" stating that "many clinical factors have been identified which are associated with an increase in cardiovascular risk following initial recovery from a myocardial infarction." Thus, one skilled in the art reading Harrison's at the time of the invention would not equate the risk factors associated with the development of myocardial infarction in the general population with the risk factors associated with a class of patients having suffered a myocardial infarction.

Still further evidence that one skilled in the art at the time of the invention would not equate treatment for general cardiovascular risk factors as sufficient for the secondary prevention of the reoccurrence of adverse cardiovascular events in a patient having suffered a myocardial infarction can be found, for example, in the American College of Cardiology and the American Heart Association Guidelines for the Management of Patients with Acute Myocardial Infarction.[1] In particular, the ACC/AHA Practice Guidelines specifically outline a "rationale and approach to pharmacotherapy" and steps for "secondary prevention" in the management of patients who have suffered a myocardial infarction. See, for example, pages 1358-1400 of the 1996 Guidelines. It is important to note that the ACC/AHA Practice Guidelines in place at the time of the invention do not provide any discussion of the administration of omega-3 fatty acids to patients who have suffered a myocardial infarction. In particular, the 1996 and 1999 Guidelines outline a "rationale

[1] See, for example, Ryan et al., "ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction)," J Am Coll Cardiol 28:1328-1428 (1996); Ryan et al., "1999 Update: ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction," J Am Coll Cardiol 34:890-911 (1999); and Antman et al., "ACC/AHA Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction: Executive Summary: A Report of the ACC/AHA Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines on the Management of Patients with Acute Myocardial Infarction)," Circulation 110:1-49 (2004).

and approach to pharmacotherapy" and steps for "secondary prevention" in the management of patients who have suffered a myocardial infarction without any mention of the administration of n-3 fatty acids. See, for example, pages 1358-1400 of the 1996 Guidelines. Thus, it is submitted that one skilled in the art at the time of the invention would not be motivated to administer fatty acids to patients who have suffered a myocardial infarction for the secondary prevention of the reoccurrence of adverse cardiovascular events.

Because the cited references fail to provide any teaching or suggestion regarding the prevention of the reoccurrence of adverse cardiovascular events in patients who have suffered a myocardial infarction as required by the instant claims, Applicants submit that a *prima facie* case of obvious cannot be established. Thus, claims 12-14, 16, 18-20, 22, 24-25, 27-28 and 30-35 are patentable over Breivik et al. (U.S. Pat. No. 5,502,077) in view of Harrison's Principles of Internal Medicine. Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

2. The Examiner is applying an improper "obvious to try" rationale

Applicants further submit that the Examiner is applying an improper "obvious to try" rationale for combining the references in support of the obviousness rejection. "An 'obvious to try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued. In re Eli Lilly & Co., 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). As described above, Breivik et al. teach the prevention of general cardiovascular risk factors including hypertension, hypertriglyceridemia and high coagulation factor VII phospholipids complex activity in otherwise healthy patients having undetected moderate hypertension without previous cardiac illness or cardiac drug use. Likewise, Harrison's teaches that such general cardiovascular risk factors may be important in the development of myocardial infarction. Nothing in the cited references describes the secondary prevention of the reoccurrence of adverse cardiovascular events in a patient who has suffered a myocardial infarction. Further, nothing in the reference provides any teaching with respect to the

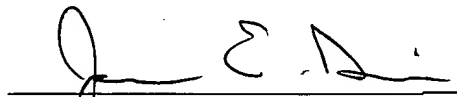
treatment of any patient having suffered a myocardial infarction or whether the administration of any of the compounds of the reference to such a patient would have any effect. Accordingly, Applicants submit that the cited references do not contain a sufficient teaching of how to prevent the reoccurrence of adverse cardiovascular events in a patient who has suffered a myocardial infarction such that the Examiner is applying an improper "obvious to try" rationale for combining the references to support an obviousness rejection. Reconsideration and withdrawal of the rejection is requested.

Conclusion

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot by this amendment. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 446-7683.

Applicants do not believe that any fee is required by the timely submission of this response. However, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 08-0750. Further, if there is any other fee deficiency or overpayment of any fees in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or credit such overpayment to Deposit Account No. 08-0750.

Respectfully submitted,



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I certify that this correspondence is being deposited with the U.S. Postal Service on **December 8, 2005** with sufficient postage as first class mail (including Express Mail per MPEP §512), and addressed to **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**.